



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,107	10/14/1999	PETER KUFER	3816-4000	6846
26161	7590	10/28/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			HELMS, LARRY RONALD	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 10/28/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/403,107

Applicant(s)

KUFER ET AL.

Examin r

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,22,28,29,31,32,38,39,42,53-56 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19,22,28,29,31,32,38,39,42,53-56 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. Claims 20-21, 34-37, 40-41, 43-52, 57-64 have been cancelled.
Claims 18-19, 22, 28-32, 38-39, 42, 53-56, 65-67 have been amended.
Claims 18-19, 22, 28-29, 31-32, 38-39, 42, 53-56, 65-67 are pending and under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains ~~some~~ NEW GROUNDS of rejection. LM

Rejections Withdrawn

4. The rejection of claims 18-22, 28-29, 31-32, 34-67 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
5. The rejection of claims 18-19, 28-29, 31-32, 38-39, 53-56, 65-67 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the amendments to the claims.
6. The rejection of claim 18-22, 28-29, 31-32, 34-67 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

Art Unit: 1642

7. The rejection of claim 28 and those depending on claim 28 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

8. The rejection of claims 18-20, 28-29, 34-40, 43-45, 48-50, 53-54, 65, 67 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffiths et al (U.S. Patent 5,885,793, 102e date 10/94) is withdrawn in view of the amendments to the claims.

9. The rejection of claims 18-20, 34-40, 43-45, 48-50, 65, 67 under 35 U.S.C. 102(e) as being anticipated by Kucherlapati et al (U.S. Patent 6,150,584, filed 10/96) is withdrawn in view of the amendments to the claims.

15. The rejection of claims 18-21, 28-31, 34-41, 43-46, 48-51, 53-55, 57-59, 61-63, 65, 67 under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al (U.S. Patent 5,885,793) as applied to claims 18-20, 28-29, 34-40, 43-45, 48-50, 53-54, 65, 67 above, and further in view of Gottlinger et al (Int. J. Cancer 38:47-53, 1986, IDS #3) is withdrawn in view of arguments presented that the 17-1A antigen is ubiquitously expressed.

Response to Arguments

10. The rejection of claims 22 and 42 under 35 U.S.C. 112, first paragraph, is maintained and made again.

The response filed 8/14/03 has been carefully considered but is deemed not to be persuasive. The response states that claim 18 states that the antibody comprises both VH and VL and as such has all 6 CDRs (see page 8 of response). In response to this argument, claim 22 has been amended to recite a VH comprising at least one CDR encoded by a portion of nucleotides 1 to 381 of SEQ ID NO:143 and a VL comprising at least one CDR encoded by a portion of 1 to 321 of SEQ ID NO:141. The claim encompasses antibodies which still have either one CDR or any "portion" of a CDR which can be as small as one nucleotide. Therefore the specification has not enabled antibodies with parts of any CDR or a single amino acid from any CDR. Therefore the rejection is maintained.

11. The rejection of claims 18-19 under 35 U.S.C. 102(b) as being anticipated by Hoess et al (Proceedings of the American Association for Cancer Research 38page 30 abstract 198, 1997, Ids #3) is maintained.

The response filed 8/14/03 has been carefully considered but is deemed not to be persuasive. The response states that Hoess et al teach an antibody that binds to immobilized antigen and did not recognize cancer cells and it did not recognize native antigen and De Kruif et al (1995) states that none of the MoPhabs against EGP-2 displayed binding to cells displaying the molecule (see page 11-12 of response). In response to this argument, Hoess et al does not teach that the antibody only bound immobilized antigen, Hoess et al teach that binders were obtained that specifically binds the antigen. In addition, it is not clear what the De Kruif et al reference has to do with

the rejection and is confusing because none of the authors on the De Kruif et al paper is on the Hoess reference and it is not clear what the MoPhabs have to do with the argument or if they are the same as those of Hoess et al.

12. The rejection of claims 18-19, 28-31, 38-39, 53-55, 65, 67 under 35 U.S.C. 103(a) as being unpatentable over Kucherlapati et al (U.S. Patent 6,150,584, filed 10/96) as applied to claims 18-20, 34-40, 43-45, 48-50, 65, 67 above, and further in view of Gottlinger et al (Int. J. Cancer 38:47-53, 1986, IDS #3) is maintained.

The response filed 8/14/03 has been carefully considered but is deemed not to be persuasive. The response states that for the same reasons above the rejection fails due to the difficulty in creating a human antibody to 17-1A (see page 14 of response). In response to this argument, although the 17-1A antigen is ubiquitously expressed, the method of Kucherlapati et al would be expected to obtain antibodies with the claimed properties by immunizing the mice with the 17-1A antigen. The method of Kucherlapati et al does not depend on a specific type of antigen and as such the 17-1A antigen would be expected to elicit an immune response in the mouse and produce antibodies to such.

The following are NEW GROUNDS of rejections

Claim Rejections - 35 USC § 112

Art Unit: 1642

13. Claims 18-19, 22, 28-29, 31-32, 38-39, 42, 53-56, 65-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 18 and 28 and those depending on these claims are indefinite for reciting "the receptor" in claim 18 or "said receptor" in claim 28 because there is insufficient antecedent basis for this limitation in the claims.

b. Claims 18 and 28 and those depending on claims 18 and 28 are indefinite for reciting "native human 17-1A antigen" because the exact meaning of the phrase is not clear. Does the phrase mean the antibody binds antigen on a cancerous cell or an antigen that is immobilized but is not denatured or binds an antigen in a "native" gel PAGE?

14. Claims 18-19, 22, 28, 29, 31, 32, 38-39, 42, 53-56, 65-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 18, 28, recite the phrase "native human 17-1A antigen". The response filed 10/14/99 which amended claim 28 to add the term "native" did not state where support for the term can be found. Likewise, the amendment filed 8/14/03 amended claim 18 to recite the term "native" and did not state where support for the term can be

Art Unit: 1642

found. As such although the specification discloses the tumor antigen 17-1A and antibodies to such, there appears to be no support for a "native" antigen. Applicants are required to provide specific support for the limitation or remove it from the claims.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

Application/Control Number: 09/403,107

Page 8


Art Unit: 1642

Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER